

## Start of the European pilot study with the Artus medical device for the treatment of urinary incontinence

- Clinical investigation centres begin patient screening and recruitment for the pilot study named 'Dry'.
- Artus is an innovative device adapted for the treatment of incontinence in women and men.
- Urinary incontinence affects 400 million people worldwide and will cost Europe €69 billion in 2023.

**Aix-en-Provence, 6 December 2023 – Affluent Medical (ISIN: FR0013333077 – Ticker: AFME), a French clinical-phase MedTech company specialising in the international development and industrialisation of innovative medical prostheses,** is announcing the start of the European pilot study, Dry, with its Artus medical device for the treatment of urinary incontinence.

The first clinical investigation centre in Prague, in the Czech Republic, has begun patients screening with a view to the initial implantation of the device. Several other centres are expected to be opened in Europe in the coming months as part of the pilot study, including Poland, where the first phase of the assessment and approval of the protocol with the ethics committee has been obtained. Affluent Medical is awaiting approval from the competent authorities in Poland to begin patient recruitment in the coming weeks. A total of 70 patients are to be recruited for the pilot and pivotal phases.

*“This is a milestone for our company and offers hope for patients in a market where there has not been real innovation in the last 40 years. The pilot phase will include male patients and we expect completion in H2 2024”, explained Sébastien Ladet, CEO of Affluent Medical. “However, we are aware that the majority of disease burden lies with women who currently do have very limited options. That is why, in a second step, we will also conduct a study for female patients later in 2024”*

The Artus medical device is the first artificial sphincter that patients can activate via remote control, for the treatment of moderate to severe urinary incontinence in both men and women. Significantly, the urinary sphincters currently on the market were not initially developed for women, even though women account for 80% of patients.

According to Optima Insights, the global market for medical devices for treating urinary incontinence (including strips, neurostimulators and artificial sphincters) is expected to reach \$4.3 billion by 2027, growing annually 11% between 2019 and 2027.

### **Publication of an international study by the European Association of Urology on the economic consequences of urinary incontinence in Europe.**

An international study by the European Association of Urology (EAU) demonstrates the economic and environmental burden of urinary incontinence in the 27 countries of the European Union, in addition to the deteriorated quality of the lives of millions of patients waiting for a new innovative treatment solution.

The pathology will cost a total of €69 billion in 2023 according to the EAU, which brings together more than 19,000 urologists and ranks as the leading organisation in Europe for urology practice, research and training.

The costs identified by the EAU include the impact of incontinence on patient health, the costs of medical consultations and products such as adult diapers, incontinence-related absenteeism from work, admissions to nursing homes, and the environmental impact of care related to this condition. If no measures are taken, incontinence is poised to become a major health problem in Europe, exacerbated by population ageing and resulting in a total economic burden of €320 billion in 2030.



In addition, despite a clearly identified medical pathway, a substantial proportion of patients with urinary incontinence receive no treatment. It is very common for these patients to handle all the expenses related to the condition, without any compensation from their healthcare system.

Urinary incontinence is a major public health problem for more than 400 million people worldwide, yet no innovations have been made in the field for over 40 years.

The pathology affects men and women alike at different stages of their lives. It is generally more prevalent among women than men, with disorders resulting from maternity, notably among younger patients (aged 25 and over), and older patients developing risks related to prostate and bladder cancer (40 and over).

Urinary incontinence has an impact on the mental health of patients, many of whom develop anxiety and depression disorders, as the pathology remains taboo for the vast majority of sufferers.

### **About Affluent Medical**

Affluent Medical is a French MedTech company, founded by Truffle Capital, with the ambition to become a global leader in the treatment of structural heart diseases, which are the world's leading cause of mortality, and urinary incontinence, which currently affects one in four adults.

Affluent Medical develops next-generation, mini-invasive, innovative, adjustable, and biomimetic implants to restore critical physiological functions. The product candidates developed by the Company are currently in preclinical and clinical studies.

Kalios, the first mitral adjustable annuloplasty ring, should be the first Affluent Medical device to be marketed.

Subject to raising the necessary funds to finance its strategy and to positive results from ongoing clinical studies, the Company's ambition is to gradually commercialize its products from the end of 2025/early 2026.

For more information, visit [www.affluentmedical.com](http://www.affluentmedical.com)

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